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10/626,390

07/24/2003

Robert H. Wham

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11/17/2006

UNITED STATES SURGICAL,
A DIVISION OF TYCO HEALTHCARE GROUP LP
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NORTH HAVEN, CT 06473

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,390

Applicant(s)

WHAM ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 28-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 28-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2006 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

1-13, 16-18, 28-40 and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller, III (5,836,943).

Miller discloses an electrosurgical system and method of treating tissue that comprises a controller for controlling the output pulses of the generator in response to measured tissue characteristics. In particular, Miller specifically teaches that impedance and/or rate of change of impedance is used to control the output of the generator in a method for treating tissue (col. 6, lines 13-61). As disclosed at column 12, lines 64 through column 13, line 10, tissue impedance is measured between pulses, and the generator is then regulated to control subsequent output pulses of the generator. Output pulses are controlled by varying the duty cycle and the magnitude of the output voltage (col. 10, lines 11-20).

Claim Rejections - 35 USC § 103

Claims 14, 15, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller, III ('943) in view of the teaching of Yates et al (5,558,671).

As addressed above, Miller discloses a system and method for controlling output pulses of a generator for coagulating (i.e. sealing) tissue by monitoring tissue impedance after a pulse (i.e. between pulses) and using the measured impedance to control subsequent pulses. Miller does not disclose the use of a look-up table as the means to arrive at the values for the subsequent pulses.

Yates et al disclose another tissue sealing device that relies on impedance feedback to control the output of an RF generator. In particular, Yates et al disclose various algorithms for controlling future application of energy based on the sensed impedance including using a look-up table to determine future energy applications (col. 8, lines 8-22).

To have provided the Miller, III system with a look-up table as a means to determine output levels for a generator in response to sensed tissue impedance would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Yates et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 and 28-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/761,524. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims and the patent claims recite the same basic method steps with only minor, obvious differences.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed October 31, 2006 have been fully considered but they are not persuasive.

It is the examiner's position that applicant is attempting to read too much of the specification into the claims as written. That is, applicant is attempting to limit the definition of limitations based on what is written in the specification rather than based on the broadest reasonable interpretation. Applicant contends that the "characteristic of

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the electrical transient" is a waveform and not a single value. First, the examiner maintains that such a strict definition is not necessarily required by the claims as provided. Second, it is the examiner's position that the Miller reference uses the same "characteristic of an electrical transient", namely the rate of change of tissue impedance, for providing control out the output of subsequent pulses. Applicant's claim 6 clearly recites that the electrical transient is tissue impedance, and the at least one characteristic of the electrical transient is a rate of change of tissue impedance. Miller clearly uses the rate of change of electrical impedance to control subsequent pulses of energy in an RF system. See column 6, lines 13+ of Miller. Applicant has acknowledged in the response that Miller monitors the rate of change of impedance (applicant's response, page 10). It is not clear how applicant can assert that Miller is not performing the same control when the same characteristic of a measured electrical transient is used. That the Miller system may be a more conventional feedback system is not deemed to be germane to the argument since there is nothing specific in the claim language that would preclude the use of a "conventional" feedback system to perform the functions set forth in the claim limitations. Applicant has not adequately described how the claimed invention measures a rate of change of impedance and uses that information to control subsequent pulses any differently than the Miller device would measure that same electrical transient (i.e. rate of change of impedance) and control subsequent pulses.

With regard to the obviousness rejection involving the combination of the teaching of Yates with the Miller reference, applicant contends that Yates fails to cure

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the deficiencies of Miller. As argued above, the examiner maintains that the claimed limitations fail to set forth structure and/or steps that clearly distinguish over the Miller control system. Applicant further asserts that the Yates look-up table is very different from applicant's look-up table. Again, it is the examiner's position that applicant is improperly importing the subject matter of the specification into the claims. Yates provides a system for providing "conventional" feedback, much like Miller. Yates specifically teach of providing a linear control feedback whereby measured parameters control the output of the generator (like Miller) or an alternative feedback whereby measured parameters are associated with a look-up table which then provides the desired feedback. The examiner maintains that the Miller reference continues to anticipate claim 1, and that there is proper motivation for providing the Miller system with a look-up table to control the feedback system in view of the teaching of Yates.

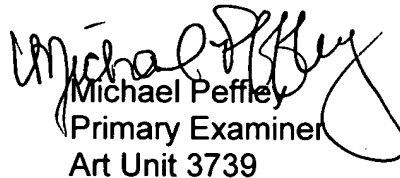
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Michael Peffley
Primary Examiner
Art Unit 3739

mp

November 10, 2006